

SHORT-TERM COURSES IN RESEARCH ETHICS

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P.T.

National Institutes of Health
Centers for Disease Control
Health Resources and Services Administration
Agency for Health Care Policy and Research
Substance Abuse and Mental Health Services Administration

Application Receipt Date: March 6

PURPOSE

The National Institutes of Health (NIH), Centers for Disease Control (CDC), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration, and the Agency for Health Care Policy and Research (AHCPR) invite applications for grants to develop, conduct, and evaluate short-term courses on ethical issues in research, particularly those involving human participants. Courses should improve the skills of biomedical, behavioral, social science, and public health researchers in identifying and addressing the ethical, legal, and social implications of their research, especially when human participants are involved.

This initiative follows a directive from the Secretary of Health and Human Services in response to President Clinton's apology to the survivors and relatives of the men who participated in the Tuskegee Syphilis Study.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Short-Term Courses in Research Ethics, is related to all twenty-two priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock Number 017-001-00474-0 or Summary Report: Stock Number 017-001-00474-1) through the

Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325
(Telephone 202-512-1800).

ELIGIBILITY

Applications may be submitted by domestic for-profit and non-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Racial and ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

Support for this program will be provided through the Continuing Education Training Grant (T15), which funds institutions to establish or expand programs of continuing professional education. Grantees may develop, offer, and/or evaluate research ethics courses ranging from three days to six weeks in duration. For organizations wanting to teach research ethics courses, such courses should be offered at least once a year. Alternatively, courses could be developed that would be made available to the student on the Internet, on video, or in another distance-learning format.

Responsibility for the planning, direction, and execution of the proposed curriculum will be solely that of the applicant.

Applicants may request up to three years of support. Allowable costs include personnel, supplies, travel and per diem for faculty, and other costs, such as printing, telephone, audio-visuals, postage, recruitment materials, and computer software. In addition, travel and per diem funds for students attending courses developed by grantees are appropriate when necessary. However, it is expected that courses will be partially supported through registration fees paid for by the attendees. Students may be recruited locally (at the grantee institution), regionally, or nationally. The indirect cost rate for T15 awards is eight percent.

RESEARCH OBJECTIVES

Background

Advances in preventing and controlling human diseases require dedicated scientists and volunteers who participate in human experimentation. Medical advances must be made through a productive and respectful partnership between researchers and participants.

The vast majority of collaborations between research participants and scientists in biomedical, behavioral, nursing, social science, and public health research that have led to important advances in health care and an improvement in the quality of life, have occurred through such a partnership. At the same time, there have been some highly visible cases of serious lapses in the ethical conduct of research involving human participants. Examples such as the Tuskegee Syphilis Study, the Willowbrook State School experiments, and the recently described Cold War radiation experiments remind the public and researchers alike that protection of participants must be of the highest priority. Balancing the dual goals of scientific merit and ethical acceptability is the responsibility of investigators who design, conduct, analyze, and disseminate the results of research.

Though researchers must have an understanding of ethical issues that pertain to research, most are presented with few opportunities to obtain and develop this knowledge. Academic training through specialized curricula related to research ethics can provide a key learning opportunity in this area; this program announcement is one step in this important direction.

Research Objectives and Scope

The objective of this grant program is to support the development, conduct, and evaluation of short-term courses on ethical issues in research, particularly research involving human participants. The courses should improve the skills of biomedical, behavioral, social science, and public health researchers in identifying and addressing the ethical, legal, and social implications of their research, especially research involving human participants. The long-term objective is to increase the number of researchers who have both awareness and skills in the ethical aspects of such research. Further, it is important that applicants propose innovative programs with fresh new approaches in the teaching and learning of research ethics.

There are many topics in research ethics that can benefit from the short course approach. The following are examples of types of courses that could be of value; they are not inclusive:

- o Courses that address practical problems arising in the design and conduct of research; examples include the use of case studies that illustrate problems faced by investigators.

- o Courses that address issues in handling the needs of specific populations participating in research, for example, women or minorities; populations with special needs, such as pregnant women, children, prisoners, or persons who may be mentally or physically challenged; or cases in which the subject's capacity or capability to make decisions freely is not clear. In the case of racial and ethnic minority groups, applicants should discuss their expertise and competency to study these populations. Curricula must reflect understanding of cultural values, beliefs, and practices.
- o Courses that address international issues in research ethics
- o Courses that explore theoretical approaches to understanding ethical, legal, and social issues in research involving human participants, such as courses describing the principle-based approach (e.g., respect for persons, beneficence, non-maleficence, and justice) to resolve issues that arise in research; and courses that explore ethics issues used in research such as risk/benefit assessments, informed consent process, privacy and confidentiality, and methods to recognize and respond to vulnerability of human participants.
- o Courses that address issues arising in the context of institutional review board (IRB) review, for example, training for IRB members in both standard areas of protocol review and new and emerging areas, including genetic epidemiology, the use of stored tissue, or the needs of special populations, such as those with questionable capacity to consent.
- o Courses that address issues arising in the conduct of international clinical trials.

All courses should be developed to meet the needs of junior or senior biomedical and behavioral researchers. Each individual area of the application should be addressed in sufficient depth to show how it significantly improves the participants' skills in addressing the ethical, legal, and social implications of research.

In both developing and teaching courses, grantees are encouraged to take an interdisciplinary approach and involve biomedical, behavioral, social science, and public health investigators experienced in addressing research ethics as well as scientists and scholars in ethics, philosophy, law or other relevant fields in the humanities. It is important for one or more of the scientists involved in the proposed program to actually have recognized expertise in the field of research ethics.

Applicants to this program should plan for wide dissemination of their educational materials and should delineate what specific mechanisms they will employ for their dissemination. In the case of internet-based materials, applicants are encouraged to submit plans on how these materials

will be advertised and made available to the appropriate community and evaluated for their effectiveness.

Applications from institutions seeking to implement a program with a large target population are encouraged to apply. While applications from institutions addressing a smaller, more local number of issues and participants are eligible to apply, priority will be given to those applications reaching a broad audience.

Grantees should also address plans to include participants from groups currently underrepresented in the field of research ethics.

Proposals for courses should also include clear plans for evaluating the effectiveness of the course(s) in terms of students' perceptions of the material and conduct of the course and, importantly, the longer-term impact as measured by participants' activities or responsibilities in their institutions in the areas of research bioethics subsequent to participating in the course. For example, assessments should address whether course participants are assuming more leadership responsibility in research bioethics as shown by membership on ethics review committees, IRBs, and other such groups at their institutions or elsewhere.

SPECIAL REQUIREMENTS

The participating agencies anticipate organizing an annual meeting of course developers and course instructors to exchange information about effective approaches to teaching research ethics, including the sharing of course materials that have been developed. Requests for funds to support the travel of the principal investigator and a small number of other course participants to the Washington, DC, area to attend this meeting should be included in the application.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that such inclusion is inappropriate with respect to the health of the subjects of the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human participants should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have

been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994.

Investigators may obtain copies from these sources or from the program staff listed under INQUIRIES.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and which is available at the following URL address: <http://www.nih.gov/grants/guide/notice-files/not98-024.html>

Investigators may obtain copies from these sources or from the program staff listed in INQUIRIES below who may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev.4/98). Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone (301) 435-0714, email: GrantsInfo@nih.gov. Applications are also available on the World Wide Web at <http://www.nih.gov/grants/forms.htm>.

For purposes of identification and processing, the PA title and number must be typed in item 2 on the face page of the application and the "YES" box must be marked.

The completed, signed original and five legible, single-sided copies of the application and five copies of the appendices must be sent or delivered to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817-7710 (for express/courier service)

Applications must be received by the application receipt date of March 6.

Only domestic institutions are eligible to apply for support under this program announcement. Potential applicants are encouraged to discuss their plans and objectives of their proposed courses with the NIH staff listed under INQUIRIES before submitting an application.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the NIH Center for Scientific Review (CSR). Incomplete applications will be returned to the applicant without further consideration.

Applications received in response to this program announcement will be reviewed for scientific and technical merit by an initial review group in the CSR, in accordance with standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score and receive a second level of review by the National Advisory Allergy and Infectious Diseases Council.

Review criteria

The review criteria for the Short-term Courses in Research Ethics will include:

- o Overall scientific and didactic merit.
- o Need for the course and its potential effectiveness in training researchers in awareness of the ethical issues associated with research.
- o Quality of the course content and adequacy of the syllabus.
- o Training, experience, and competence of the faculty in the ethical issues applicable to this program.

- o Criteria for selecting participants and for awarding scholarships, for publicizing the availability of the course to the target audience of active researchers, and plans to reach out to underrepresented investigators. Adequate plans for the recruitment of underrepresented participants should be contained in the application.
- o Plans for evaluating the effectiveness and the extent of dissemination of the course.
- o Plans for disseminating curricula to a broad audience.
- o Adequacy and availability of any necessary institutional facilities, such as the library and computer resources.
- o Appropriateness of the requested budget for the proposed course.

AWARD CRITERIA

Funding decisions will be based on the recommendations of the initial review group and the National Advisory Allergy and Infectious Diseases Council regarding scientific and programmatic merit as well as the availability of funds.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be directed to:

Milton J. Hernandez, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 4B04
Bethesda, MD 20892-7640
Telephone: (301) 496-3775
FAX: (301) 402-0369
Email: mh35c@nih.gov

Direct inquiries regarding fiscal matters to:

Barbara Huffman
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases

6003 Executive Boulevard, Room 3C25

Bethesda, MD 20892-7640

Telephone: (301) 496-3821

FAX: (301) 402-0369

Email: bh23q@nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos.93.855 and 93.856. Awards are made under the authority of Title III, Section 301 of the PHS Act as amended. The Code of Federal Regulations, Title 42 Part 52 and Title 45 part 74, are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)